

I. AMENDMENT

Please make the following amendments:

In the Claims:

Please cancel claims 20, 22-23, 25, 29 and 32 without prejudice or disclaimer.

Please amend claims 6, 8-10, 17-18, 27 and 30-31 as follows:

- A1
6. (Amended) The corn plant of claim 2, wherein said plant is further defined as comprising a gene conferring male sterility.
8. (Amended) The tissue culture according to claim 7, the cells or protoplasts of the tissue culture having been isolated from a tissue selected from the group consisting of leaves, pollen, embryos, roots, root tips, anthers, silks, flowers, kernels, ears, cobs, husks, and stalks.
- A2
9. (Amended) A corn plant regenerated from the tissue culture of claim 7, wherein the regenerated plant expresses all the morphological and physiological characteristics of inbred line LH321.
10. (Amended) A corn plant with all of the physiological and morphological characteristics of corn inbred LH321, wherein said corn plant is produced by a tissue culture process using the corn plant of claim 5 as the starting material for said process.
17. (Amended) A method for producing inbred LH321 seed, representative seed of which have been deposited under ATCC Accession No. _____, comprising:
- A3
- a) planting a collection of seed comprising seed of a hybrid, one of whose parents is inbred LH321, said collection also comprising seed of said inbred;
 - b) growing plants from said collection of seed;
 - c) identifying inbred parent plants;
 - d) controlling pollination in a manner which preserves the homozygosity of said inbred parent plant; and
 - e) harvesting the resultant seed.
18. (Amended) The process of claim 17 wherein step (c) further comprises identifying plants with decreased vigor.

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27. (Amended) A method for producing a corn plant that contains in its genetic material one or more transgenes, comprising crossing the corn plant of claim 26 with either a second plant of another corn line, or a non-transformed corn plant of the line LH321, wherein progeny are produced, so that the genetic material of the progeny that result from the cross contains the transgene(s) operably linked to a regulatory element.
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30. (Amended) A method for developing a corn plant in a corn plant breeding program using plant breeding techniques comprising employing a corn plant, or its parts, as a source of plant breeding material comprising: using the corn plant, or its parts, of claim 2 as a source of said breeding material.
31. (Amended) The method for developing a corn plant in a corn plant breeding program of claim 30 wherein plant breeding techniques are selected from the group consisting of: recurrent selection, backcrossing, pedigree breeding, restriction fragment length polymorphism enhanced selection, genetic marker enhanced selection, and transformation.
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II. RESPONSE TO OFFICE ACTION

A. Power of Attorney

It is stated that the Revocation of Power of Attorney was not entered because only the first page was received. In response, it is noted that a complete copy of the Power of Attorney that was submitted is attached herewith as **Appendix C**. Entry of the Power of Attorney is respectfully requested.

B. Status of the Claims

Claims 1-32 were filed with the original application. Claims 20, 22-23, 25, 29 and 32 have been canceled without prejudice or disclaimer. Claims 6, 8-10, 17-18, 27 and 30-31 have been amended herein. A marked copy of the amendments is provided in **Appendix A**. A clean

copy of the pending claims following entry of the amendments is provided in **Appendix B**. Claims 1-19, 21, 24, 26-28 and 30-31 are now pending and presented for reconsideration.

C. Objection to the Specification

The specification has been objected to based on the lack of information regarding the deposit of seed of inbred LH321. In response, Applicants note that the specification will be amended to insert the seed deposit information upon the allowance of the case.

D. Claim Objection

The Action objects to claims 1, 17 and 19 for inclusion of a blank line. In response, it is noted that the claims will be amended to insert the seed deposit information upon the allowance of the case.

E. Rejection of Claims Under 35 U.S.C. §112, First Paragraph

(1) The Action rejects claims 1-32 under 35 U.S.C. §112, first paragraph, for lack of enablement based on the need for a deposit of seed of corn variety LH321.

In response, Applicants note that a deposit of 2,500 seeds of the inbred LH321 will be made with the ATCC upon the allowance of the case. The deposit will be made in accordance with the terms and provisions of 37 C.F.R. §1.808 relating to deposits of microorganisms. The deposit will be made for a term of at least thirty years or at least five years after the most recent request for furnishing of a sample of the deposit is received by the depository or for the effective life of the patent, whichever is longer. A declaration certifying that the deposit meets the criteria

set forth in 37 C.F.R. §1.801-1.809 will be provided and the claims will be amended to recite the accession number for the deposit.

In light of the foregoing, Applicant respectfully requests that the rejection be withdrawn.

(2) The Action rejects claims 6 and 11-32 under 35 U.S.C. §112, first paragraph, for allegedly lacking an adequate written description in the specification. Applicants respectfully traverse the rejection.

With respect to claims 20, 22-23, 25, 29 and 32, it is first noted that the claims have been canceled without prejudice or disclaimer and thus the rejection of these claims is now moot. With respect to the remaining claims, the claimed subject matter has been described in full compliance with the first paragraph of 35 U.S.C. §112, first paragraph. In particular, the specification provides a description of sufficient structural characteristics of hybrid plants having inbred corn plant LH321 as one parent to satisfy the written description requirement. For example, the specification describes, in Tables 1-4, four hybrids that were produced using LH321 as one parent. Described in the tables are the mean yield, percentage moisture, stalk lodging, root lodging, percent of dropped ears, plant height and ear height for these hybrids. This information, combined with the descriptions of the genetic and morphological characteristics of LH321 in the specification, is more than adequate to provide a description of hybrid plants and seeds derived from corn plant LH321 in compliance with the written description requirement. While the claims are directed to a genus of plants, these four hybrids constitute a representative set of species describing the genus based on the shared structural characteristics of the members of the genus.

Because corn plant LH321 is an inbred corn plant, all hybrid plants having LH321 as a parent will contain the same genetic contribution from LH321 and thus will be genetically

distinct and identifiable from any other corn plant on this basis. That is, because LH321 is an inbred corn plant, all hybrid corn plants derived therefrom must inherit exactly half of the genetic material of corn plant LH321. All hybrid plants derived from LH321 will thus be genetically distinct with respect to this genetic contribution. The Federal Circuit has noted that such shared structural features possessed by members of a genus is important to the written description requirement. *The Regents of The University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997) (noting that a name alone does not satisfy the written description requirement where “it does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, *as one can do with a fully described genus, visualize or recognize the identity of the members of the genus*” (emphasis added)). Here, all of the members of the claimed genus of hybrids having LH321 as one parent share the identical structural feature of having the genetic complement of LH321. One of skill in the art could thus readily identify the members of the genus. The written description requirement has therefore been fully complied with.

The Action also rejects claims to corn plant LH321 which has been transformed with one or more transgenes. However, such plants are fully described by way of the description of corn plant LH321 and representative transgene species, including the accompanying phenotypic effect of the transgenes. Examples of just some of the transgenes and the associated phenotypic traits described in the specification include the following: genes that confer resistance to herbicides or antibiotics such as (a) a neomycin phosphotransferase II (nptII) gene, isolated from transposon Tn5, conferring resistance to kanamycin, (b) a hygromycin phosphotransferase gene conferring resistance to the antibiotic hygromycin, (c) streptomycin phosphotransferase, gentamycin acetyl transferase and aminoglycoside-3'-adenyl transferase, conferring resistance to

antibiotics; screenable marker genes including, (a) β -glucuronidase, (b) luciferase, (c) chloramphenicol acetyltransferase, and (d) Green Fluorescent Protein (GFP); genes that confer resistance to pests or disease including (a) the tomato Cf-9 gene for resistance to *Cladosporium fulvum*, (b) the tomato Pto gene for resistance to *Pseudomonas syringae* pv., (c) an *Arabidopsis* RSP2 gene for resistance to *Pseudomonas syringae*, (d) a *Bacillus thuringiensis* insecticidal protein gene, (e) a vitamin-binding protein such as avidin, (f) an enzyme inhibitor, for example, a protease or proteinase inhibitor or an amylase inhibitor, and (g) an insect-specific hormone or pheromone such as an ecdysteroid and juvenile hormone; a mutant 5-enolpyruvyl-3-phosphokimate synthase (EPSP) or aroA gene conferring resistance to glyphosate; antisense stearyl-ACP desaturase to increase stearic acid content of the plant; a phytase-encoding gene enhancing breakdown of phytate, adding more free phosphate to the transformed plant; and a gene coding for an enzyme that alters the branching pattern of starch such as an α -amylase or tomato invertase gene.

The foregoing examples constitute a representative set of species supporting a description of the genus of transformed LH321 plants. To conclude otherwise would limit Applicants to that subject matter described *ipsis verbis* in the specification. This position is expressly contradictory to Federal Circuit precedent. *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (stating that the written description requirement does not require an applicant to "describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (citations omitted)). While Applicants have not described every possible single species of transgenes introduced into LH321, this is not required to provide a written description of a genus. *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994).

In view of the foregoing, Applicants have fully complied with the written description and removal of the rejection under 35 U.S.C. §112, first paragraph, is thus respectfully requested.

(3) The Action rejects claims 6 and 11-32 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. In particular, the Action alleges that the specification does not adequately describe the corn variety LH321 comprising a transgene and methods of use thereof. Applicants respectfully traverse.

It is first noted that all that is required to satisfy the enablement requirement of 35 U.S.C. §112, first paragraph, is that Applicants teach one reasonably skilled in the art how to make and use the claimed invention without undue experimentation. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). The specification has done this and thus fully meets the requirement.

Claim 26, for example, is directed to corn plant LH321 or parts thereof “wherein the plant or parts thereof have been transformed so that its genetic material contains one or more transgenes operably linked to one or more regulatory elements.” The Action appears to reject this and the other claims as allegedly failing to adequately describe the corn plant having been transformed so that its genetic material contains one or more transgenes. However, this allegation is not understood. As set forth above, Applicants must only teach one of skill in the art to make and use the invention. Applicants have more than adequately done so. For example, the specification provides corn line LH321, which will be deposited upon the indication of otherwise allowable subject matter. The specification also describes numerous plant transformation techniques that are known in the art at pages at pages 29-31, including: *Agrobacterium*-mediated transformation; microprojectile-mediated transformation; sonication of

target cells; liposome or spheroplast fusion; electroporation of protoplasts and whole cells and tissues; and direct uptake of DNA into protoplasts using CaCl_2 precipitation, polyvinyl alcohol or poly-L-ornithine. No allegation has been made that any of these techniques are not enabling for transformation of maize.

The specification further describes numerous coding and regulatory sequences for transformation into corn plant LH321 using the transformation techniques described including numerous examples of plant disease resistance genes, *Bacillus thuringiensis* protein genes, genes that confer resistance to a herbicide; genes that confer or contribute to a value-added trait, inducible promoters, constitutive promoters, tissue-specific promoters, and signal sequences for targeting proteins to subcellular compartments. This teaching is more than adequate to teach one of skill in the art to introduce one or more transgenes into corn variety LH321.

In an attempt to support the rejection, the Action cites several references alleged to show the difficulty of making male sterile or single locus converted plants. However, no basis has been given to show that these references have any relevance to *corn* plants. Hunsperger deals with petunias; Kraft with sugar beets and Eshed with Tomatoes. No allegation has been made that the references refer to corn plants. The relevance of the references to the claimed invention has therefore not been established as is specifically required to establish a *prima facie* case of non-enablement.

It is finally noted that the Action provides no basis for doubting the sufficiency of the teaching in Applicants' specification and thus the enablement of Applicants' claims. A mere allegation that Applicants have not met the enablement requirement of 35 U.S.C. §112, first paragraph, will not support a rejection, "[o]therwise, there would be no need for the applicant to

go to the trouble and expense of supporting his presumptively accurate disclosure.” *In re Marzocchi*, 169 U.S.P.Q. at 370. Absent such a basis, the rejection must fail.

In view of the foregoing Applicants respectfully request the removal of the rejection

F. Rejection of Claims Under 35 U.S.C. §112, Second Paragraph

The Action rejects claims 6, 8, 20, 23, 25-29 and 31 under 35 U.S.C. §112, second paragraph as allegedly being indefinite for failing to particularly point out the subject matter which Applicants regard as the invention. Applicants responses to the rejections are set forth below in the order they appear in the Action:

(1) Rejection of claim 6:

Applicants note that claim 6 has been amended to specify that the plant is “further defined as comprising a gene conferring male sterility.” The amendment does not narrow the claims and, accordingly, Applicants do not intend to disclaim any subject matter through the amendment. It is believed that the rejection is now moot in light of the amendment.

(3) Rejection of claim 8:

Applicants note that the claim has been amended to replace “being from” with “having been isolated from.” The amendment does not narrow the claims and, accordingly, Applicants do not intend to disclaim any subject matter through the amendment. It is believed that the rejection is now moot in light of the amendment.

(4) Rejection of claims 20, 23, 25 and 29:

Applicants respectfully traverse the rejection but note that, in the interest of compact prosecution of the case, the subject claims have been cancelled without prejudice or disclaimer. The rejection is thus now moot.

(5) Rejection of claim 26 and claims dependent thereon:

Applicants respectfully traverse. Claim 26 depends from claim 2 and therefore incorporates all of the limitations of claim 2, but further specifies the added characteristic of one or more transgenes. The claim therefore contains a reference to the claim from which it depends, contains a further limitation of the subject matter claimed in the main claim; and incorporates all elements of the claim from which it depends. The claim is therefore in proper dependent form pursuant to 37 C.F.R. §1.75(c) and is not confusing. The claim is further authorized pursuant to 35 U.S.C. §112, fourth paragraph. The claim is therefore fully definite and in compliance with the statutes.

In view of the foregoing, Applicants respectfully request removal of the rejection.

(6) Rejection of claim 31:

In response, Applicants note that the preamble of claim 31 has been amended to specify “The method for developing a corn plant in a corn plant breeding program of claim 30.” The amendment does not narrow the scope of the claims and, accordingly, Applicants do not intend to disclaim any subject matter through the amendment. It is believed that the rejection is now moot in light of the amendment.

G. Rejection of Claims Under 35 U.S.C. §102(b)

The Action has rejected claims 1-5 under 35 U.S.C. §102(b) as allegedly anticipated or, in the alternative, obvious over a prior variety. Applicants respectfully traverse.

No basis for the rejection has been presented. The rejection is made based on the allegation that the claimed inbred “appears” to be identical, yet not a single trait of the cited variety is compared to the claims. Under 35 U.S.C. § 102(b) it is the burden of the Office to show that each and every element as set forth in the claim is found in the prior art. *Verdegaal*

Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

The identical invention must be shown in as complete detail as is contained in the claim.

Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

This has not been done and the rejection must therefore fail.

To the extent that alleged unexpressed inherent characteristics form the basis of an anticipation rejection, it is noted by Applicants that these characteristics must necessarily flow from the disclosure. *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991) ("To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill."). The Action has thus clearly failed to meet the burden under 35 U.S.C. §102(b).

In view of the foregoing Applicant respectfully requests removal of the rejection.

H. Rejection of Claims Under 35 U.S.C. §102(e)/103(a)

The Action has rejected claims 20, 22-23, 25-26, 29 and 32 under 35 U.S.C. §102(b)/103(a) as allegedly anticipated or, in the alternative, obvious over a prior variety. Applicants respectfully traverse.

Of the cited claims, only claim 26 is currently pending. The claim is directed to the corn plant, or parts thereof, of claim 2, wherein the plant or parts thereof have been transformed so that its genetic material contains one or more transgenes operably linked to one or more regulatory elements. No basis has been provided to support the rejection of this claim. The

rejection is made based on a broad allegation that the reference might anticipate the claims without showing that it does do so. However, what *could* happen is irrelevant. Under 35 U.S.C. § 102(b) it is the burden of the Office to show that each and every element as set forth in the claim is found in the prior art. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). This has not been done and the rejection must therefore fail.

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Similarly, in order to establish a *prima facie* case of obviousness under 35 U.S.C. §103, three criteria must be met: (1) there must be some motivation or suggestion in the cited prior art

or in the knowledge generally available to one of skill in the art to combine the teachings to arrive at the invention, (2) there must be a reasonable expectation of success, and (3) the prior art must teach or suggest all claim limitations. *See In re Vaeck*, 947 F.2d 488, 20 USPQ 2d 1438 (Fed. Cir. 1991), *see also*, M.P.E.P. § 2142. All three of these criteria are missing in the instant rejection. First, there is no motivation or suggestion in the prior art to arrive at the invention and no rationale for such a motivation has been alleged in the Action. The rejection thus relies on an “obvious to try” type rationale. This approach has been rejected by the Federal Circuit. *See In re O’Farrell*, 853 F.2d 894, 903. Second, one of skill in the art would have no reasonable expectation of success in arriving at the invention. Finally, the Action has not shown that the prior art teaches or suggests all of the claim limitations. Without such a teaching of all of the claim limitations, one of skill in the art would lack the guidance necessary to arrive at the invention.

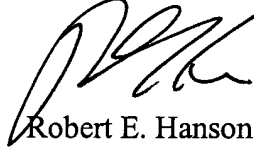
In view of the foregoing Applicant respectfully requests removal of the rejection.

I. Conclusion

This is submitted to be a complete response to the referenced Office Action. In conclusion, Applicant submits that, in light of the foregoing remarks, the present case is in condition for allowance and such favorable action is respectfully requested.

The Examiner is invited to contact the undersigned at (512)536-3085 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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